



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5966]

Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the final guidance entitled "Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff." This guidance document describes policies that FDA intends to use to implement the new Breakthrough Devices Program, established by the 21st Century Cures Act (Cures Act). The Breakthrough Devices Program supersedes and combines elements from FDA's Expedited Access Pathway (EAP), which was intended to facilitate the development and expedite review of certain devices that demonstrate the potential to address unmet medical needs, as well as the Priority Review Program, which implemented statutory criteria for granting priority review to premarket approval applications (PMAs) and applied those criteria to other types of premarket submissions for medical devices. This guidance is intended to clarify certain principles and features of the new program, the designation criteria for Breakthrough Devices, the designation request review process, the process for withdrawing from the program, as well as the recommended information device manufacturers should provide in their designation request for entrance into the program.

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-5966 for "Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential."

Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Maureen Dreher, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.1545, Silver Spring, MD 20993-0002, 301-796-2505.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance to describe policies that FDA intends to use to implement section 515B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e-3, as created by section 3051 of the Cures Act (Pub. L. 114-255) and amended by section 901 of the FDA Reauthorization Act of 2017 (Pub. L. 115-52) (the "Breakthrough Devices Program"). The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, premarket notification (510(k)) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

As part of the Breakthrough Devices Program, FDA intends to provide interactive and timely communication with the sponsor during development and throughout the review process for devices designated as Breakthrough Devices under section 515B(d)(1) of the FD&C Act and prioritize the review of associated Q-submissions, investigational device exemption (IDE) applications, PMAs, certain PMA supplements, De Novo requests, and/or 510(k)s. In addition, for Breakthrough Devices subject to PMA, FDA may consider the amount and nature of data that may be collected in the postmarket setting, rather than premarket, and the extent of uncertainty that may be appropriate in the benefit-risk profile at the time of approval. Getting the right balance between premarket and postmarket data collection--specifically, where appropriate, a greater reliance on postmarket collection--can reduce the extent of premarket data submission. Collectively, these and the other principles of the program described in this guidance are

intended to support a least-burdensome approach for expediting patient access to Breakthrough Devices.

The Breakthrough Devices Program supersedes the EAP, which launched in 2015. The Breakthrough Devices Program contains features of the EAP as well as the Innovation Pathway (first piloted in 2011; pilot is now discontinued), both of which were intended to facilitate the development and expedite the review of breakthrough technologies.

The Breakthrough Devices Program also supersedes the Priority Review Program, which implemented statutory criteria for granting priority review to PMA submissions for medical devices, applied those criteria to other types of premarket submissions for medical devices, and included standard procedures to achieve an efficient priority review process.

FDA considered comments received on the draft guidance that appeared in the *Federal Register* of October 25, 2017. FDA revised the guidance as appropriate in response to the comments. This document supersedes the guidance document "Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions," issued on April 13, 2015.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the "Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1833 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo classification process	0910-0844
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff"	Q-submissions	0910-0756
820	Current Good Manufacturing Practice (CGMP); Quality System	0910-0073

	(QS) Regulation	
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Dated: December 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-27433 Filed: 12/18/2018 8:45 am; Publication Date: 12/19/2018]